DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 10 1997

James R. Hager
Infusaid, Inc.
Pfizer Hospital Products Group
1400 Providence Hwy.
Norwood MA 02062

Docket # 94P-0001

Dear Mr. Hager:

This is in response to your petition dated December 31, 1993, requesting that the Commissioner of Foods and Drugs designate the Vapor-Pressure Powered Implantable Infusion Pump an essential device which would be exempt from sections 610(b) and (d) of the Clean Air Act (CAA).

The agency has reviewed your petition. However, upon review of the CAA and its implementing regulations, and in consultation with the Environmental Protection Agency (EPA), FDA has determined that the use of the class I or class II ozone-depleting substance in your product is not a use that is subject to the non-essential products ban under the CAA. Therefore, it is unnecessary to amend 21 CFR 2.125(e) to include Vapor-Pressure Powered Implantable Infusion Pumps.

Although not subject to the CAA's non-essential products ban, your product will be affected by the Montreal Protocol (an international agreement to establish a world-wide ban on production of ozone-depleting substances, with limited exemptions for the supply for certain approved products), and EPA's corresponding phase-out regulations. Manufacturers seeking approval for their products under the Montreal Protocol must be nominated, by individual countries, to an international panel for consideration. To apply for nomination to the Montreal Protocol, you may contact Ms. Chris O'Donnell of the EPA at (202) 233-9079.

If you choose to apply to the EPA to nominate your product for approval under the Montreal Protocols, you may wish to attach a copy of this response for EPA's consideration. I hope this response has been helpful.

Sincerely,

Joseph A. Levitt

Joseph A. Levitt
Deputy Director for
Regulations and Policy,
Center for Devices and
Radiological Health

cc: Chris O'Donnell, EPA

94P-0001

PDN 1